REMARKS

This is a full and timely response to the outstanding non-final Office Action mailed February 24, 2006. Through this response, claims 83, 91, 98, 100, 105–107, 109, and 150 have been amended; claims 121-122 and 129-130 have been canceled without prejudice, waiver, or disclaimer; and claims 55-82, 134-135, 145-147 and 151 remain withdrawn. Reconsideration and allowance of the application and pending claims are respectfully requested.

Claim Objections

Claim 150 has been objected to for the following informalities: The claim language appears to end after "comprising" without setting forth limitations that further limit the parent claim.

In response to the objection, Applicants assert that the claim language was indeed submitted on page 11 of the preliminary amendment, as well as language for claims 151 – 182, which have also been included here. It appears that the Examiner may not have received or reviewed page 11 of the preliminary amendment.

The missing language has been included in the claims of the instant Response. Applicants respectfully submit that the claims are not objectionable and respectfully request that the objection be withdrawn.

Claim Rejections - 35 U.S.C. § 112, First Paragraph

Claims 121, 122, 129, and 130 have been rejected under 35 U.S.C. § 112, first paragraph, for the objections cited in the Office Action against Applicants' specification. In that claims 121-122 and 129-130 have been canceled, those objections have been rendered moot.

Claim Rejections - 35 U.S.C. § 112, Second Paragraph

Claims 91 and 105-107 have been rejected under 35 U.S.C. § 112, second paragraph, as being allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention. In particular, the Examiner states that

> The phrases "ink jet technology" (claim 91), "thermal ink jet technology" (claim 105), "piezoelectric ink jet technology" (claim 106) and "electrostatic actuated inkjet technology" (claim 107) do not clearly and sufficiently describe the structural features and steps of the method. By referring to a technology in general, applicant is not sufficiently describing which aspects of the particular technology are incorporated and how they are incorporated in the claimed invention.

Office Action at 4.

In response to the rejection, Applicant has amended claims 91 and 105-107. In view of those amendments, it is respectfully asserted that claims 91 and 105-107 define the invention in the manner required by 35 U.S.C. § 112. Accordingly, Applicant respectfully requests that the rejections to these claims be withdrawn.

Applicant wishes to clarify that the foregoing amendments are cosmetic in nature and are not made as a condition for obtaining a patent. Applicant further submits that these amendments are non-narrowing and, pursuant *to Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 122 S. Ct. 1831 (2002), no prosecution history estoppel arises from the amendments. *See also Black & Decker, Inc. v. Hoover Svc. Ctr.*, 886 F.2d 1285, 1294 n. 13 (Fed. Cir. 1989); *Andrew Corp. v. Gabriel Elecs., Inc.*, 847 F.2d 819 (Fed. Cir. 1988); *Hi-Life Prods. Inc. v. Am. Nat'l Water-Mattress Corp.*, 842 F.2d 323, 325 (Fed. Cir. 1988); *Mannesmann Demag Corp. v. Eng'd. Metal Prods. Co., Inc.*, 793 F.2d 1279, 1284-1285 (Fed. Cir. 1986); *Moeller v. Ionetics, Inc.*, 794 F.2d 653 (Fed. Cir. 1986).

Claim Rejections - 35 U.S.C. § 102(b)

Claims 83-100, 108, 109, 111-122, 126-130, 136, 140, 141, and 148-150 have been rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by *Jacobsen et al.* ("*Jacobsen*," U.S. Pat. No. 5,860,957). First, Applicants would like to note that claims 111-117 were canceled in the preliminary amendment, and thus the rejection of these claims is improper. Additionally, Applicants respectfully traverse this rejection on the grounds that *Jacobsen* does not teach or suggest every element of independent claims 83 and 91.

Anticipation requires that each and every element of the claimed invention be disclosed in a single prior art reference. *See e.g., In re Paulsen,* 30 F.3d 1475, 31 USPQ 2d 1671 (Fed. Cir. 1994); *In re Spada,* 911 F.2d 705, 15 USPQ 2d 1655 (Fed. Cir. 1990). The *Jacobsen* reference does not disclose, teach, or suggest all of the claimed elements. Specifically, *Jacobsen* does not teach or suggest the feature of amended claim 83 of "wherein each bioactive composition droplet is less than or equal to 100 picoliters" and amended claim 91 of "dispensing the bioactive composition from an inkjet dispenser."

First, with respect to claim 83, *Jacobsen* does not teach or suggest dispensing a bioactive composition in as small of droplet volumes, as recited in the claim. Specifically, *Jacobsen* discloses that "the drug is delivered through a 100 micrometer nozzle" (col. 11, line 27) and "potent drugs and formulations active at low (in the range of 100 to 200 microliter) injection volumes." (col. 11, lines38-39) (emphasis added). In contrast, the instant claims recite droplets in the picoliter range, which is six orders of magnitude smaller than that disclosed in *Jacobsen.*[1] For at least this reason alone, *Jacobsen* does not teach or suggest all of the features of independent claim 83. Applicants therefore respectfully request that the rejection be withdrawn.

[1] A picoliter is 1×10^{-12} liters, while a microliter is 1×10^{-6} liters.

Second, with respect to claim 91, *Jacobsen* does not teach or suggest dispensing the bioactive composition from an inkjet dispenser, as recited in the claim. *Jacobsen* discloses a fluid jet delivery system that does not function at all like an inkjet dispenser. Specifically, *Jacobsen* states the following when describing its jet delivery system:

> When a drug is to be administered, the control panel connected to the drug storage/delivery system causes a high energy density thermochemical propellant in the drug delivery system to be ignited. The propellant gas that is produced creates pressure which ejects the drug formulation from the reservoir container. Depending upon the drug delivery route required for the drug being administered, the propellant will either: (i) force a hypodermic needle into the subcutaneous space or into a patient's muscle tissue, inject the drug from the storage container through the needle embedded in the patient, and withdraw the needle; (ii) force the drug from the storage container through a jet nozzle that injects the drug the into subcutaneous space or intramuscularly; (iii) force the drug from the storage container onto a patch in contact with the skin for passive transdermal delivery....

Jacobsen at col. 3, lines 4-17. It is clear from the foregoing that jet delivery system of *Jacobsen* requires a propellant gas that creates pressure to eject the drug. In contrast, as described in the specification, various inkjet dispensing devices do not require such a propellant gas, and operate by heating resistors or expanding resistors and thereby creating a regulated, controlled, and precise droplet of the bioactive. *See Specification, e.g.*, at pages 7-10, 17-18, and 21-22. For at least this reason alone, *Jacobsen* does not teach or suggest all of the features of independent claim 83. Applicants therefore respectfully request that the rejection be withdrawn.

Dependent claims 84-90, 92-100, 108, 109, 118-122, 126-130, 136, 140, 141, and 148-150 are believed to be allowable for at least the reason that these claims depend from allowable independent claims 83 and 91, respectively. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988).

Additionally and notwithstanding the foregoing allowability of claims 83 and 91, the dependent claims recite further features and/or combinations of features (as is apparent by

examination of the claims themselves) that are patentably distinct from the prior art of record. Hence, there are other reasons why this dependent claim is allowable and some of these reasons are set forth hereafter, as examples. For example, claim 105 recites the steps of using a thermal inkjet dispenser. These steps are not taught or suggested by *Jacobsen*. In addition, and by way of further example, claim 106 recites the steps of using a piezoelectric inkjet dispenser, which steps are also not taught or suggested by *Jacobsen*. Further, claim 136 recites, "applying a bioactive composition attracting agent to a treatment location on the cutaneous surface of the subject." The Examiner has not demonstrated where in the prior art this feature is found. Therefore, for at least these reasons also, the rejection of the dependent claims should be withdrawn.

Response To Claim Rejections Under 35 U.S.C. §103(a)

(1) Claims 123-125 and 131-133 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over *Jacobsen* (U.S. Patent No. 5,860,957). Applicants respectfully traverse this rejection. First, dependent claims 123-125 and 131-133 are believed to be allowable for at least the reason that these claims depend from allowable independent claims 83 and 91, respectively.

Second, it is well established law that, for a proper rejection of a claim under 35 U.S.C. §103 as being obvious based upon a single reference, the reference must disclose, teach, or suggest, either implicitly or explicitly, all elements/features/steps of the claim at issue. *See, e.g., In Re Dow Chemical*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988), and *In re Keller*, 208 U.S.P.Q.2d 871, 881 (C.C.P.A. 1981). In the instant case, the Examiner has not met a *prima facie* case of obviousness by demonstrating how it would have been obvious to one of ordinary skill in the art to employ accelerometers as sensors. Instead, the Examiner attempts to cure these deficiencies of the *Jacobsen* reference by relying on generalized statements that these features

"would have been obvious to one of ordinary skill in the art to employ accelerometers as sensors 60." *Office Action* at 8. If the Examiner is taking official notice of various claim limitations as being "well-known," the MPEP defines the standard for taking official notice. As provided in MPEP § 2144.03 (emphasis added):

> ***Official notice without documentary evidence to support an examiner's conclusion is permissible only in some circumstances.*** While "official notice" may be relied on, these circumstances should be rare when an application is under final rejection or action under 37 CFR 1.113. Official notice unsupported by documentary evidence should only be taken by the examiner where the facts asserted to be well-known, or to be common knowledge in the art are capable of instant and unquestionable demonstration as being well-known. As noted by the court in *In re Ahlert*, 424, F.2d 1088, 1091, 165 USPQ 418, 420 (CCPA 1970), the notice of facts beyond the record which may be taken by the examiner must be "capable of such instant and unquestionable demonstration as to defy dispute" (citing *In re Knapp Monarch Co.*, 296 F.2d 230, 132 USPQ 6 (CCPA 1961)).

As provided in MPEP § 2144.03 (emphasis added):

> If applicant adequately traverses the examiner's assertion of official notice, ***the examiner must provide documentary evidence in the next Office action*** if the rejection is to be maintained. See 37 CFR 1.104(c)(2).

Applicant traverses the Examiner's assertion of official notice of each of the items in the Office Action. In particular, Applicant traverses the assertion that "would have been obvious to one of ordinary skill in the art to employ accelerometers as sensors 60 as an accclerometer measures its own acceleration and can thus be used as a reference baseline for the calculation of the user's heartbeat and breathing rates." *Office Action* at 8. Applicant submits that the Examiner is taking statements from Applicant's own specification to arrive at the conclusion that this feature of Applicant's invention would be obvious based on the combination of references. For example, the instant Detailed Description section states, "a mechanical sensor such as an accelerometer 225 may be used, for instance to monitor physical parameters of a subject, such as

a mechanical sensor positioned to monitor heartbeats, breathing for shortness-of-breath/excessively-fast- -breathing, or, in a more practical daily application, to monitor a subject's activity." *Specification* at page 20, paragraph [068]. Applicant submits this is impermissible hindsight reconstruction and requests that the Office provide documentary evidence in the prior art in the next Office Action as to how it would be obvious to provide an monitor portion of a jet dispenser as recited in claim 123, a mechanical sensor as recited in claim 124, or an accelerometer as recited in claim 125, in combination with the apparatus of *Jacobsen*.

(2) Claims 102-107 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over *Jacobsen* ('957) in view of *Hayes et al.* (U.S. Patent No. 6,325,475). Applicants respectfully traverse this rejection. First, dependent claims 102-107 are believed to be allowable for at least the reason that these claims depend from allowable independent claims 83 and 91, respectively.

Second, in order for a claim to be properly rejected under 35 U.S.C. §103, the teachings of the prior art reference must suggest all features of the claimed invention to one of ordinary skill in the art. *See, e.g., In re Dow Chemical*, 837 F.2d 469, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988); *In re Keller*, 642 F.2d 413, 208 U.S.P.Q. 871, 881 (C.C.P.A. 1981).

Specifically with respect to combining prior art references, "[t]he PTO has the burden under section 103 to establish a prima facie case of obviousness. It can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references." *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988).

"Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. Under section 103, teachings of references can be combined only if there is some suggestion or incentive to do so." *ACS Hospital Systems, Inc., v. Montefiore Hospital*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984) (emphasis added). In addition, "[t]here must be some reason, suggestion, or motivation found in the prior art whereby a person of ordinary skill in the field of the invention would make the combination." *In re Oetiker*, 977 F.2d 1443, 1447, 24 USPQ 2d 1443 (Fed. Cir. 1992) (emphasis added).

In the instant case, there is no suggestion or motivation in the references to combine them. Indeed, both the drug dispensers themselves, and the applications/uses of the drug dispensers of the two references are very different. *Jacobsen* discloses a fluid jet dispenser (which is not an inkjet dispenser, as discussed above), whereas *Hayes* discloses an inkjet dispenser. Additionally, *Jacobsen* discloses using its fluid jet dispenser for cutaneous drug delivery, whereas *Hayes* discloses using its inkjet dispenser "to micro-dispense of airborne materials...for inhalation...." *Hayes* at col. 1, lines 14-16. As noted in the instant specification:

> Inhaled drugs can be absorbed directly through the mucous membranes and epithelium of the respiratory tract, thereby minimizing initial inactivation of bioactive substances by the liver. Inhalational delivery can also provide drugs directly to therapeutic sites of action (such as the lungs or the sinuses). This mode of administration has been particularly effective for the delivery of pulmonary drugs (such as asthma medications) and peptide based drugs (usually via intranasal administration), using metered dose inhalers (MDIs). However, MDIs often require coordinating inspiration with actuation of the MDI, and some patients are not able to master this technique. Moreover, patients still often forget to take the medication at prescribed times, or for the necessary period of time to achieve clinical goals. Other patients inadvertently or inappropriately use medications, leading to hospitalizations, morbidity, and even death.

Specification at 1. Thus, the specification makes very clear that there are special considerations, advantages, and drawbacks to using inhalational delivery of drugs. None of these considerations apply directly to cutaneous delivery of drugs. Thus, it is improper to take these two references that are directed to two very different aspects of the broad art of drug delivery and combine them. For at least this reason, the rejection of claims 102-107 should be withdrawn.

Comment on Information Disclosure Statement (IDS)

Applicants note that the Examiner crossed through several of the foreign patent references in Applicants' Information Disclosure Statement (IDS). Applicants are unsure why the Examiner has not considered the cited foreign references, and respectfully request that the Examiner send a corrected IDS, indicating that all references have been considered in the instant application. The Examiner is reminded that under 37 C.F.R. 1.98(d)(1), references submitted in a parent patent application do not have be re-submitted in an application that relies on the parent application for an earlier effective filing date under 35 U.S.C. 120.

Prior Art Made of Record

The prior art made of record has been considered, but is not believed to affect the patentability of the presently pending claims.

Canceled Claims

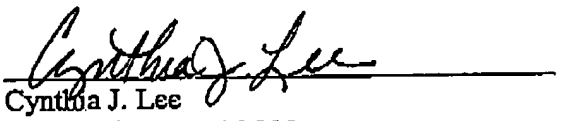
As identified above, claims 121-122 and 129-130 have been canceled from the application through this Response without prejudice, waiver, or disclaimer. Applicants reserve the right to

present these canceled claims, or variants thereof, in continuing applications to be filed subsequently, and do not intend to dedicate the subject matter to the public.

CONCLUSION

Applicants respectfully submit that Applicants' pending claims are in condition for allowance. Favorable reconsideration and allowance of the present application and all pending claims are hereby courteously requested. If, in the opinion of the Examiner, a telephone conference would expedite the examination of this matter, the Examiner is invited to call the undersigned attorney at (770) 933-9500.

Respectfully submitted,



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